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10/767,675

01/29/2004

Tom McHale

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/767,675 | Applicant(s) MCHALE ET AL. | |
| | Examiner Ryan J. Severson | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/8/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection (because of the arguments presented in the appeal brief of 10/27/2009) of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Particularly, the previous rejection is withdrawn because upon conferencing, it was determined that it would not have been obvious to modify Matthews et al. with Wolvek et al.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 5, 6, 15-20, 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolvek et al. (4,276,874).** Wolvek et al. disclose a catheter (see figure 11) comprising a catheter shaft, an inflation balloon (the combination of elements 112 and 114), having proximal and distal waist portions and proximal and distal cone portions. The catheter further includes a catheter tip comprising a guidewire lumen (Examiner notes here that the claims do not require the lumen to pass through the entire catheter tip, merely that a lumen be present). The catheter tip includes a central shaft portion (at location 116), a first recessed portion (124) that extends around the entire circumference of the tip and a second recessed portion (120) that also extends around the entire circumference of the tip. The first portion is oriented beneath the distal cone (in the same manner as shown in figure 3, where the recessed portion is

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extended) and the second portion is oriented beneath the proximal cone of the balloon (see figure 11). The catheter is more flexible in the recessed regions than the central shaft portion (considered the “second region” as required in claim 15).

4. **Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Fulton (6,074,374).** Fulton discloses a catheter comprising a catheter shaft (61), a balloon (64), and a catheter tip having a recessed portion (67) oriented beneath the balloon. The tip further includes a proximal end (at the left side of figure 3), a distal end (71), a main shaft portion (61), and a distal shaft portion (at 65 in figure 3). The catheter has a first region (the recessed portion) that is more flexible than the second region (the main shaft portion) because of the reduced size.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 2-4, 7-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Fulton (6,074,374).** Wolvek et al. fail to disclose a marker or hub disposed beneath the balloon. Attention is drawn to Fulton, who teaches a marker or hub (69) is disposed beneath the balloon to allow the balloon to be placed in the body in the correct place (centered at the treatment site) using well-known visualization techniques. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the marker

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hub of Fulton on the shaft beneath the balloon of Wolvek et al. to allow to correct placement of the catheter and balloon at the treatment site.

7. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Fulton (6,074,374) as applied to claim 9 above, and further in view of Follmer et al. (5,728,065).** The combination of Wolvek et al. and Fulton fails to disclose a marker disposed flush with the outer surface of the catheter tip. Attention is drawn to Follmer et al., who teach a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a low profile and can be imaged because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert mold flush the marker of Follmer et al. with the tip of the combination of Wolvek et al. and Fulton to create a tip that has a low profile yet can be located and guided using conventional imaging techniques.

8. **Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Follmer et al. (5,728,065).** Wolvek et al. fail to disclose a spring stiffener. Attention is drawn to Follmer et al., who teach a catheter tip may have two regions (122 and 114) with the second region (spring 114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tip of Wolvek et al. of two regions wherein the first region is more

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flexible than the second region, as taught by Follmer et al., to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

9. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Imran et al. (5,766,203).** Wolvek et al. fail to disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al., who teach a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of Wolvek et al. as a stent delivery catheter, as taught by Imran et al., to deliver a stent to provide permanent support to a weakened vessel.

10. Regarding claim 22, Imran et al. teach a stent mounted about the balloon (see figure 8C).

11. Regarding claim 23, the stent of Imran et al. is an inflation expandable stent (see column 8, lines 36-41).

12. Regarding claim 24, the Imran et al. stent is self-expanding (column 8, line 56).

13. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Hamilton et al. (6,514,228).** Wolvek et al. fail to disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton et al., who teach an inner catheter tip may have a triangular cross section if desired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to shape the tip of Wolvek et al. in a triangular shape, as taught by Hamilton et al., as an obvious alternative to the circular catheter shape.

14. **Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolvek et al. (4,276,874) in view of Chee et al. (5,906,606).** Wolvek et al. fail to disclose the second region comprises stiffeners that are carbon fibers. Attention is drawn to Chee et al., who teach a catheter tip may be reinforced with carbon fibers (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon fibers of Chee et al. in the second region of Wolvek et al. to create a device that has the rigidity desired in the second region but reduces the weight of the device by using the carbon fibers instead of larger ribbons.

Response to Arguments

15. Applicant's arguments with respect to claims 1 and 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J. Severson/
Examiner, Art Unit 3731
1/18/10

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
1/19/10